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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,934	12/31/2003	Thomas E. Tarara	53279-US-CNT	1899
1095	7590	06/25/2009		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER SCHLIENTZ, LEAH H	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			06/25/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/750,934	<b>Applicant(s)</b> TARARA ET AL.	
	<b>Examiner</b> Leah Schlientz	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38,39,41,44,47-56,58,60,62-68,103-105 and 109-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38,39,41,44,47-56,58,60,62-68,103-105 and 109-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgement of Receipt***

Applicant's Response, filed 4/15/2009, in reply to the Office Action mailed 1/15/2009, is acknowledged and has been entered. Claims 38, 54 and 104 have been amended. Claims 23-37, 84-102, 107 and 108 have been cancelled. Claims 109-111 are newly added. Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 are pending and are examined herein on the merits for patentability.

### ***Response to Arguments***

Applicant's arguments filed 4/15/2009 have been fully considered but they are not persuasive, for reasons set forth hereinbelow.

Any rejection not reiterated herein has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68 and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent), as evidenced by Weickert *et al.* (US 2002/0177562), Weidmann *et al.* (*J. Controlled Release*, 2000, 65(1-2), p. 43-7), and Didriksen (WO 00/01365), for reasons set forth in the previous Office Action.

Applicant argues on pages 8-12 of the Response that Weers et al, Weickert et al, Wiedmann et al, and Didriksen do not render the independent claims unpatentable. Applicant asserts that the claims are drawn to a pharmaceutical formulation comprising particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose, and that Weers et al does not disclose particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Instead, Weers et al discloses particulates where a solution of an active agent (as opposed to particles of active agent) is dispersed within a phospholipid matrix. In one example, Weers et al discloses budesonide particles within a matrix (see Example V). However, in this example, the budesonide is combined with lactose (see page 12 lines 1-4). Claim 38 explicitly excludes lactose-containing particles from its ambit. Accordingly, Weers et al does not disclose, teach or suggest the invention as set forth in claim 38.

This is not found to be persuasive. It is noted that Example V demonstrates lactose, but Weers also clearly teaches that conventional DPIs comprise powdered formulations and devices where a predetermined dose of medicament, either alone or in a blend with lactose carrier particles, is delivered as an aerosol of dry powder for inhalation (paragraph 0042). Weers further teaches that by providing particles with very low bulk density, the minimum powder mass that can be filled into a unit dose container is reduced, which eliminates the need for carrier particles. That is, the relatively low density of the powders provides for the reproducible administration of relatively low

Art Unit: 1618

dose pharmaceutical compounds. Moreover, the elimination of carrier particles will potentially minimize throat deposition and any "gag" effect, since the large lactose particles will impact the throat and upper airways due to their size (paragraph 0049). Therefore, regarding the presence of lactose in the formulation of Example V, one would have been motivated to eliminate lactose from the formulation since Weers specifically teaches that elimination of lactose carrier particles has particular desirable benefits (e.g. lack of gag effect). A reference is not limited to what is taught by the examples. See MPEP 2123. Patents are relevant as prior art for all they contain. "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

### ***New Grounds for Rejection***

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly added claims 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent), as evidenced by Weickert *et al.* (US 2002/0177562), Weidmann *et al.* (*J. Controlled Release*, 2000, 65(1-2), p. 43-7), and Didriksen (WO 00/01365), as previously applied to claims 38, 39, 41, 44, 47-56, 58, 60, 62-68 and 103-105, for reasons set forth in the previous Office Action.

### ***Double Patenting***

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105 and 109-111 are provisionally rejected on the ground of non-statutory obviousness-type double patenting over the claims of copending Application No. 11/187,757 for reasons set forth in the previous Office Action.

### ***Conclusion***

No claims are allowed at this time.

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

LHS